EXHIBIT 166

Case: 1:17-md-02804-DAP Doc #: 1960-60 Filed: 07/23/19 2 of 8. PageID #: 139436



Attachment 1

U. S. Department of Justice
Drug Enforcement Administration
New Orleans Field Division
3838 North Causeway Boulevard
Suite 1800, Three Lakeway Center
Metairie, Louisiana 70002

www.dea.gov

GENERICS BIDCO I, LLC 130 Vintage Drive Huntsville, Alabama 35811

Dear Mr. Robert Mills:

During the month of August 2010, Investigators of the Birmingham Drug Enforcement Administration (DEA) Diversion Group conducted an in-depth investigation of your firm. This investigation revealed record keeping violations pertaining to the handling of controlled substances. The violations noted are as follows:

- 1. Failure to maintain on a current basis a complete and accurate record of each controlled substance sold by your firm. Section 1304.21(a) of Title 21 Code of Federal Regulations requires that registrants maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.
- 2. Failure to record dates of receipt on which the controlled substances are actually received by your firm. Section 1304.21(d) of Title 21 Code of Federal Regulations require registrants to record dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer.

This letter is formal notification that your failure to maintain adequate records and controls for controlled substances constitutes violations of the Controlled Substance Act. At this time, you are being afforded the opportunity to comply with the requirements of the Controlled Substance Act, which were outlined by the Investigators. For your convenience, a copy of the aforementioned sections of the Code of Federal Regulations has been enclosed for your information.

Please advise the Birmingham DEA Office at 920 18th Street North, Birmingham, Alabama 35203 in writing within thirty (30) days of the action taken of planned to correct these violations. If you have any questions concerning this matter, please contact Group Supervisor Patricia Millier at (205) 321-8601.

Sincerely

Jimmy S. Fox III
Special Agent in Charge

GENERICS BIDCO I, LLC

Page 2

Louis A. Lejarz

Acting Diversion Program Manager

Enclosure

130 Vintage Drive Huntsville, AL 35811



T 256.859.4011 F 256.859.4021

September 30, 2010

Patricia Millier Group Supervisor Birmingham Office U.S. Drug Enforcement Administration 920 18th Street North Birmingham, Alabama 35203

Dear Ms. Millier:

In response to the letter sent by Special Agent Jimmy S. Fox III, which we received on September 24, 2010 (Attachment 1), we have set forth below our responses to the two specific record keeping issues detected by the Investigator during an inspection of our Distribution Center conducted during the week of August 2, 2010. We hope that you will find these responses sufficient to verify the corrective action we already have taken and demonstrate our compliance with the Controlled Substances Act.

Failure to maintain on a current basis a complete and accurate record of each controlled substance sold by
your firm. Section 1304.21(a) of Title 21 Code of Federal Regulations requires that registrants
maintain on a current basis a complete and accurate record of each such substance manufactured,
imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no
regulation shall be required to maintain a perpetual inventory.

<u>Inspectional Observation:</u> In reviewing DEA Form 222 number 094078834, it was observed that the form was voided only on copies 1 and 2, but there was no indication of void or canceled on copy 3.

Assignable Cause: The DEA Form 222 is a three part attached form with two carbon inserts, one between copies 1 and 2 and the other between copies 2 and 3. DEA Form 222 number 094078834 was filled out and signed, and copy 3 was separated from copies 1 and 2 as required. Subsequent to the completion of the form, but prior to shipment, it became necessary to void the form and to prepare a new form for different quantities of product to be shipped. Copies 1 and 2 of DEA Form 222 number 094078834 were voided, as required. Since the carbon had been removed from between copies 2 and 3, the "void" was not recorded on copy 3. Copy 3 was attached to copies 1 and 2 and stored in the proper DEA Form 222 log book.

Corrective Action: The DEA Investigator's observation was explained to the employee who is responsible for filling in the DEA Form 222s and who had made the error. The employee was also provided additional training regarding the appropriate procedures for completing DEA Form 222s to ensure that each copy properly records all information as required, including the appropriate procedure for voiding a Form 222. This training was documented and is included as Attachment 2. The word 'void' has also been recorded on copy 3 of DEA Form 222 number 094078834.

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Page 2 09/30/10

> 2. Failure to record dates of receipt on which the controlled substances are actually received by your firm. Section 1304.21(d) of Title 21 Code of Federal Regulations require registrants to record dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer.

Inspectional Observation: In reviewing DEA Form 222 number 101602195, it was observed that an error was made recording the quantity of Oxycodone 15mg tablets received in the Distribution Center. The corrected quantity was carried down to line 10 on the form; however the employee did not include a date on line 10 because she had never crossed out the date on line 4.

Assignable Cause: The employee who completed DEA Form 222 number 101602195 initially recorded in the designated block of line 4 the incorrect quantity of product received. The employee appropriately lined out, initialed, and dated the incorrect quantity. Because there no longer was room on line 4 for the employee to write in the correct quantity, the employee recorded the correct quantity below on line 10, marked it with an asterisk, and wrote the number '4' to indicate that this value represented the corrected quantity for line 4 above. The employee did not include a date on line 10 because she did not cross out the date on line 4 and concluded that the date still recorded on line 4 would be associated with the quantity now recorded on line 10.

Corrective Action: The DEA Diversion Investigator's observation was explained to the employee responsible for completing DEA Form 222s. The employee has also been provided additional training regarding the appropriate procedures for completing DEA Form 222s. This training was documented and that documentation is included in this response as Attachment 2. DEA Form 222 number 101602195 was corrected, and a copy of the corrected form is included with this response as Attachment 3.

We hope that our responses adequately address the inspection observations and demonstrate the Company's compliance with the Controlled Substances Act. However, if you have any questions or require any further documentation in order to verify our compliance, please contact us immediately.

Sincerely,

Robert S. Mills

President

Generics Bidco I, LLC dba Qualitest Pharmaceuticals

130 Vintage Drive

Huntsville, AL 35811

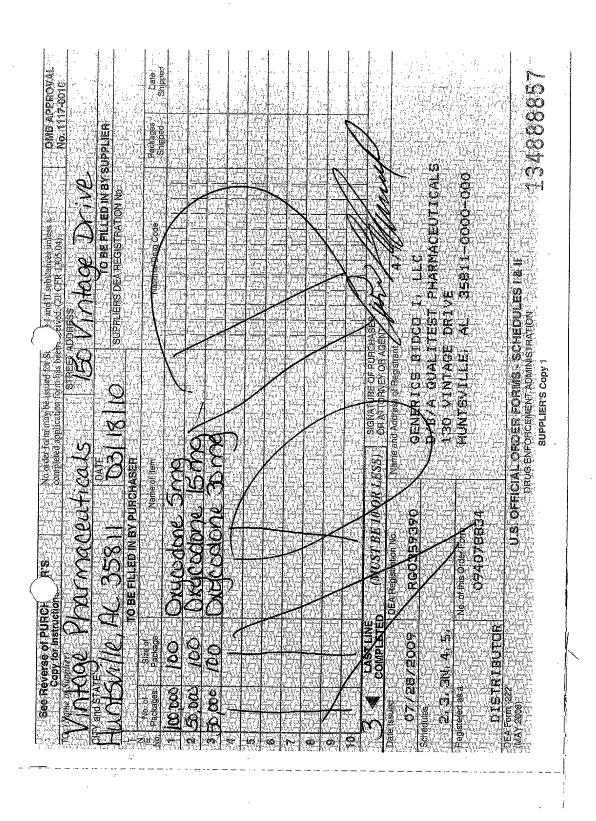
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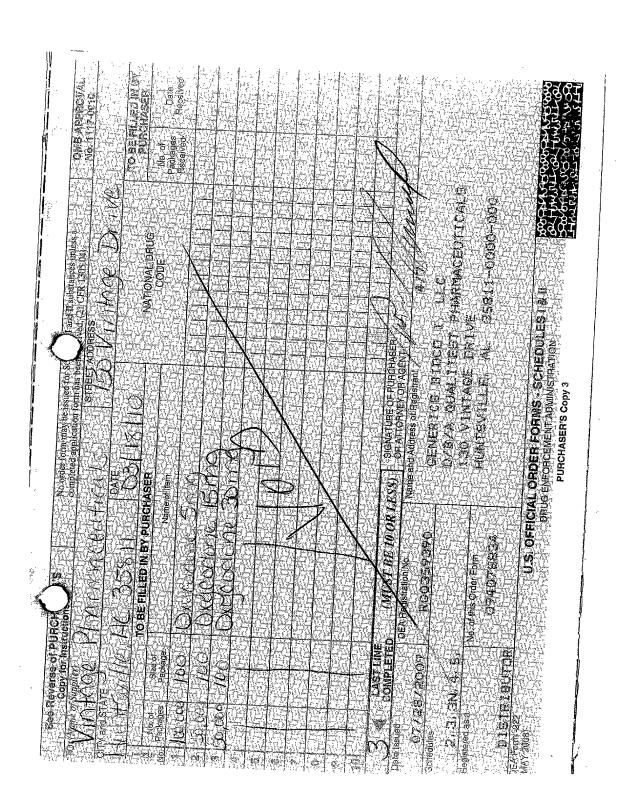
rmills@qualitestrx.com

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